

EDWARD J. MARKEY  
7TH DISTRICT, MASSACHUSETTS  
www.house.gov/markey

ENERGY AND COMMERCE COMMITTEE  
RANKING MEMBER  
SUBCOMMITTEE ON  
TELECOMMUNICATIONS AND  
THE INTERNET  
RESOURCES COMMITTEE

**Congress of the United States**  
**House of Representatives**  
**Washington, DC 20515-2107**

2108 RAYBURN BUILDING  
WASHINGTON, DC 20515-2107  
(202) 225-2836

DISTRICT OFFICES:  
5 HIGH STREET, SUITE 101  
MEDFORD, MA 02155  
(781) 396-2900  
188 CONCORD STREET, SUITE 102  
FRAMINGHAM, MA 01702  
(508) 875-2900

December 17, 2001

The Honorable Tommy G. Thompson  
Secretary  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Mr. Thompson:

I am writing in regard to a report in the November 26, 2001 issue of Inside Energy, which stated that Los Alamos National Laboratory (LANL) received a shipment of virulent anthrax from Northern Arizona University on October 26, 2001, even though LANL is not authorized to receive such shipments. I am also concerned that LANL may have misled the Centers for Disease Control and Prevention (CDC) about its possession of this dangerous material.

As you may know, in 1996 I introduced H.R. 3033, the "Biological Weapons Control Act of 1996" with former Representative John Kasich, and Senator Hatch (S. 1606). The bill imposed requirements for the transfer of select agents and was later signed into law as part of the Anti-terrorism and Effective Death Penalty Act of 1996 (Section 511 of Public Law 104-132). If Congress had not passed this law, America would be largely in the dark with respect to who transfers or receives bioagents in this country. Last month the House took one more step in the battle against bioterrorism by voting to expand the 1996 law to require that all select agents be registered. I am concerned that LANL (and Northern Arizona University) may have violated the 1996 law. Consequently, I ask for your assistance in answering the following questions:

1. Current regulations require any laboratory working with virulent anthrax samples to either be classified as a Biosafety Level-3 laboratory by the CDC or obtain a CDC exception permit or registration to handle the materials. LANL's laboratory reportedly is only classified as a Biosafety Level-2 laboratory, and it reportedly did not obtain a CDC exception permit or registration prior to receiving the shipment of virulent anthrax.
  - a) Is it your opinion that LANL and/or Northern Arizona University violated the law in their decisions to request/transfer the sample?
  - b) Did Northern Arizona University properly label the sample in accordance with the law?

- c) Please fully describe the obligations of both a Requestor of a select agent and a Transferor of a select agent to ensure that the shipment complies with the law.
  - d) What are the maximum penalties associated with the type of violation made by LANL and Northern Arizona University? Will they be imposed? If not, why not?
2. Current regulations require both a Requestor and a Transferor of a select agent to complete the appropriate sections of the transfer form EA-101.
  - a) Please provide copies of the form filled out by both LANL and Northern Arizona University, indicating which sections were incorrect or inaccurate.
  - b) Current regulations state that falsification of this form would be a federal criminal offense. Did LANL or Northern Arizona University falsify this form? If so, have you notified federal criminal law enforcement authorities, and if not, why not?
3. A November 21, 2001 Occurrence Report filed by LANL states that "LANL was in transition through internal processes to implement procedures to operate under an exception of 42 CFR 72.6 that allows transfer of select agent materials in support of law enforcement activities."
  - a) Please provide all documentation associated with LANL's application for an exception to the law.
  - b) Has this exception since been granted, and if so, when and under what circumstances?
4. The November 21, 2001 Occurrence Report also states that "the CDC has rendered a preliminary ruling that, because the work was in direct support of law enforcement, the shipment was exempt from the registration limitation, and was in full regulatory compliance."
  - a) Is it true that the CDC determined that LANL was in full regulatory compliance **at the time it received the sample**, simply because it was performing work in direct support of law enforcement? Please provide a copy of this preliminary ruling.
  - b) Has a final ruling been issued? If so, please provide a copy.
  - c) Is there a process in place to ensure that a particular laboratory is performing work in support of law enforcement activities, and that it is able to perform such work without risking public health and safety, prior to receiving an exemption from the registration requirements of the law? What is that process?
  - d) Did LANL comply with that process prior to receiving the shipment of virulent anthrax from Northern Arizona University? If not, does that mean that either or both of LANL and Northern Arizona University violated the law?
  - e) Have any other facilities or entities been granted an exemption from the registration limitation in order to perform work in direct support of law enforcement? If so, were they allowed to receive select agent materials prior to obtaining such an exemption from the CDC? Was the process by which these exemptions were granted different from that used by LANL, and if so, how?
5. On what date (and by whom) was CDC first informed of the unauthorized anthrax shipment at LANL?

Thank you very much for your attention to this important matter. Please provide your responses by close of business January 2, 2002. Should you have any questions or concerns, please have your staff contact Dr. Michal Freedhoff of my staff at 202-225-2836.

Sincerely,

A handwritten signature in black ink, reading "Edward J. Markey". The signature is written in a cursive style with a large, stylized "M" and "K".

Edward J. Markey